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Exhibit R-2, RDT&E Budget Item Justification: PB 2011 Navy									DATE: February 2010		
APPROPRIATION/BUDGET ACTIVITY 1319: Research, Development, Test & Evaluation, Navy BA 5: Development & Demonstration (SDD)				R-1 ITEM NOMENCLATURE PE 0604771N: Medical Development							
COST (\$ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
Total Program Element	39.457	56.692	12.337	0.300	12.637	14.054	14.083	11.056	11.357	Continuing	Continuing
0933: Medical/Dental Equipment Dev	7.544	9.847	12.337	0.300	12.637	14.054	14.083	11.056	11.357	Continuing	Continuing
9999: Congressional Adds	31.913	46.845	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	172.667
A. Mission Description and Budget Item Justification											
A. Mission Description and Budget Item Justification: The purpose of this item is to develop biomedical equipment and related techniques to reduce morbidity; to enhance the logistic feasibility of modern medical care for combat casualties; to sustain casualties for evacuation to fixed medical facilities for definitive care; and to ensure that personnel are medically qualified for military duty. Each work unit undertaken in this project has a military requirement. Efforts are justified based upon military payoff and cost benefit. There is a strong potential for dual use, technology transfer, and biotechnology firms/industry participation in the projects.											
B. Program Change Summary (\$ in Millions)											
	FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total						
Previous President's Budget	39.725	9.888	0.000	0.000	0.000						
Current President's Budget	39.457	56.692	12.337	0.300	12.637						
Total Adjustments	-0.268	46.804	12.337	0.300	12.637						
• Congressional General Reductions		-0.236									
• Congressional Directed Reductions		0.000									
• Congressional Rescissions	0.000	0.000									
• Congressional Adds		47.040									
• Congressional Directed Transfers		0.000									
• Reprogrammings	0.000	0.000									
• SBIR/STTR Transfer	-0.268	0.000									
• Program Adjustments	0.000	0.000	12.337	0.000	12.337						
• Rate/Misc Adjustments	0.000	0.000	0.000	0.300	0.300						
Congressional Add Details (\$ in Millions, and Includes General Reductions)										FY 2009	FY 2010
Project: 9999: Congressional Adds											

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APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>Development & Demonstration (SDD)</i>		R-1 ITEM NOMENCLATURE PE 0604771N: <i>Medical Development</i>	
<u>Congressional Add Details (\$ in Millions, and Includes General Reductions)</u>		FY 2009	FY 2010
Congressional Add: <i>Biocidal Wound Dressings</i>		0.000	1.195
Congressional Add: <i>Deployment Health and Chronic Disease Surveillance</i>		0.000	0.797
Congressional Add: <i>Integrated Psycho-Social Health Care Demonstration Program</i>		0.000	0.996
Congressional Add: <i>Management of Lung Injury by Micronutrients</i>		0.000	1.195
Congressional Add: <i>Multivalent Dengue Vaccine Program</i>		0.000	1.275
Congressional Add: <i>National Functional Geonomics Center Colloborating Site</i>		0.000	3.187
Congressional Add: <i>Simplified Orthopedic Surgery</i>		0.000	4.222
Congressional Add: <i>Wound Care Research (transferred from Defense Health Program)</i>		0.000	12.946
Congressional Add: <i>MILITARY DENTAL RESEARCH</i>		5.984	5.975
Congressional Add: <i>Advanced Molecular Medicine Initiative</i>		1.995	0.797
Congressional Add: <i>ON-DEMAND CUSTOM BODY IMPLANTS/PROSTHESIS FOR INJU</i>		1.596	1.593
Congressional Add: <i>HAMPTON UNIVERSITY CANCER TREATMENT INITIATIVE</i>		7.977	3.983
Congressional Add: <i>Mobile Oxygen, Venilation & External Suction (Mo</i>		1.197	2.709
Congressional Add: <i>US NAVY PANDAMIC INFLUENZA VACCINE PROGRAM</i>		1.596	1.593
Congressional Add: <i>PENN STATE CANCER INSTITUTE</i>		2.792	0.000
Congressional Add: <i>Composite Tissue Transplanation for Combat Wounded</i>		1.995	1.992
Congressional Add: <i>Heal The Force</i>		2.792	0.000
Congressional Add: <i>Topical Homostat Effectiveness Study</i>		0.798	0.000
Congressional Add: <i>US Navy Cancer Vaccine Program</i>		2.393	2.390
Congressional Add: <i>Disposable Biocidal Medical Masks for NAMRU Evalua</i>		0.798	0.000
Congressional Add Subtotals for Project: 9999		31.913	46.845
Congressional Add Totals for all Projects		31.913	46.845

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<p><u>Change Summary Explanation</u></p> <p>Technical: Not applicable.</p> <p>Schedule: Not applicable.</p> <p>FY11 from previous President's Budget is shown as zero because no FY11-15 data was presented in President's Budget 2010.</p>		

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APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>Development & Demonstration (SDD)</i>				R-1 ITEM NOMENCLATURE PE 0604771N: <i>Medical Development</i>				PROJECT 0933: <i>Medical/Dental Equipment Dev</i>			
COST (\$ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
0933: <i>Medical/Dental Equipment Dev</i>	7.544	9.847	12.337	0.300	12.637	14.054	14.083	11.056	11.357	Continuing	Continuing
Quantity of RDT&E Articles	0	0	0	0	0	0	0	0	0		
A. Mission Description and Budget Item Justification The purpose of this item is to develop biomedical equipment and related techniques to reduce morbidity; to enhance the logistic feasibility of modern medical care for combat casualties; to sustain casualties for evacuation to fixed medical facilities for definitive care; and to ensure that personnel are medically qualified for military duty. Each work unit undertaken in this project has a military requirement. Efforts are justified based upon military payoff and cost benefit. There is a strong potential for dual use, technology transfer, and biotechnology firms/industry participation in the projects.											
B. Accomplishments/Planned Program (\$ in Millions)											
						FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total	
Medical/Dental Equipment Dev <i>FY 2009 Accomplishments:</i> PreClinical Trials for FDA approval of an Infusible Hemostatic Agent - Initiated final preclinical trials of platelet derived hemostatic agents. Two candidate agents will be compared in a parallel effort. The outcomes will drive subsequent FDA Safety/Efficacy Trials of the infusible hemostatic agent selected from preclinical tests. The agent is designed for applications to non-compressible injuries. Heterotopic Ossification Incidence - Researched clinical procedures for reducing the incidence and severity of Heterotopic Ossification (HO) associated with traumatic injury. Identified potential modifications of clinical causes and timing of interventions. The Use of the Vacuum Assisted Wound Closure Device and Quantitative Bacteriology in Extremity Wound Closure transitioning to Wound Management Program - Finalized Clinical Protocols for use						7.544	9.847	12.337	0.300	12.637	

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B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
of cytokine/growth factor expression in reducing associated debridement and irrigation. Initiated transition to standard clinical practice at medical treatment facilities.						
Monitoring, Oxygen Ventilation and External Suction (MOVES) System - Conducted reconfiguration of MOVES to reduce weight and cost for subsequent production runs. Incorporated joint service requirements. Continued Configuration Management of MOVES anesthesia module.						
Forward-Deployable Dental Dressing Developmental/Operational Test and Evaluation - Conducted Final Field Testing of ruggedized delivery system for the novel dental dressing.						
Restoration of Endodontically-Treated or Compromised Teeth to Prevent or Rehabilitate Tooth Fracture Using Computer-Aided Direct Ceramic/Composite Full-Coverage Restoration - Initiated transition of CEREC protocols to clinical practice.						
Cybertech Cric Cricothyroidotomy Device - Conducted late Developmental Test & Evaluation for human factors and ruggedization of Low Rate Initial Production cricothyroidotomy devices. This is a joint program with the USMC and US Army.						
Refinement and Development of Medical Planning Factors Among the Services - Finalized modelling technologies for medical planning. Updated and augmented algorithms using data collected from available data sources. Transitioning final product to medical planners.						
Transition Projects from Force Health Protection Future Naval Capability - Initiated Development, Testing, and Evaluation program for transition products from the Office of Naval Research 6.3 Advanced Development program. Focus will be on transition of novel hemostatic agents (e.g. infusible hemostatics and field/first responder devices).						
Establishing a 3D Craniofacial Image Protocol and Pre-Injury Database - Continued refinement of the pre-traumatic 3D image database for soft and hard tissue for use to re-establish structures for						

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B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
reconstruction of craniofacial abnormalities or traumatic injuries. Resulting images will be used for surgical guides to decrease OR time and increase predictability of surgical outcomes.						
Validation of a Readiness to Fly Assessment Tool - Continued Validation of an operational readiness assessment tool. The tool is computer-based and used to assess an aviator's readiness to fly. It is based on cognitive abilities crucial to heavy mental workload of aircraft operations and the effects of fatigue.						
Development of the Medical Force Planning Factors - Measured the effectiveness of combat casualty medical care and preventive gear.						
Clinical Evaluation of a Vaxfectin TM - Formulated Tetravalent Dengue DNA Vaccine (VTDDV) - Continued clinical investigations trials on four serotypes of dengue.						
Evaluation of HemCon's Dental Dressing for Controlling Hemorrhage - Finalize the assessment of the stability/shelf-life of the product under extreme environmental operating conditions.						
FY 2010 Plans:						
Clinical Evaluation of a Vaxfectin TM - Formulated Tetravalent Dengue DNA Vaccine (VTDDV) - Continue clinical investigations trials on four serotypes of dengue.						
Phase I Clinical Trials for FDA approval of an Infusible Hemostatic Agent - Complete Phase I Safety Trials of the infusible hemostatic agent selected from preclinical tests. The agent is designed for applications to non-compressible injuries. Transition to US Army Medical Materials Development Agency for Phase II.						
Mobile Oxygen Ventilation and External Suction (MOVES) Anesthesia - Continue Development of MOVES anesthesia module.						

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B. Accomplishments/Planned Program (\$ in Millions)						
		FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Joint Development Projects with MARCORSYSCOM Medical Acquisition - Initiate Joint Development Testing and Evaluation program for medical products and equipment. Finalize development for USMC Procurement. Transition Projects from Force Health Protection Future Capability - Initiate Development, Testing, and Evaluation program for transition products from the Office of Naval Research 6.3 Advanced Development program. Focus will be on transition of novel hemostatic agents (e.g. infusible hemostatics and field/first responder devices).						
FY 2011 Base Plans: Joint Development Projects with MARCORSYSCOM Medical Acquisition - Initiate Joint Development Testing and Evaluation program for medical products and equipment. Finalize development for USMC Procurement. Transition Projects from Force Health Protection Future Capability - Initiate Development, Testing, and Evaluation program for transition products from the Office of Naval Research 6.3 Advanced Development program. Focus will be on transition of novel hemostatic agents (e.g. infusible hemostatics and field/first responder devices). USMC Participation in the National Institute of mental Health (NIMH) Suicide Study - Provide annual report on risks and protective factors associated with increased suicides among Marines, while supporting the development of evidence-based prevention, assessment, and treatment services. Assessment and reporting will be in accordance with MOU developed with Department of the Army.						
FY 2011 OCO Plans: Combined Maritime Acoustic Device and Optical (Laser) Field Test - Based on a 5th Fleet requirement, an evaluation of various commercial off-the-shelf (COTS) and government-off-the-shelf (GOTS) Non-Lethal Weapons (NLW) technology is required to determine the effectiveness of a combined Acoustic and Laser device as a long range NLW hailing and warning device. The future acquisition to deploy these types of systems in-theater will be determined by the Armed Services based on this evaluation.						

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B. Accomplishments/Planned Program (\$ in Millions)								
				FY 2009	FY 2010	FY 2011 Base	FY 2011 OCO	FY 2011 Total
Accomplishments/Planned Programs Subtotals				7.544	9.847	12.337	0.300	12.637
C. Other Program Funding Summary (\$ in Millions) N/A								
D. Acquisition Strategy N/A								
E. Performance Metrics Milestone reviews.								

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COST (\$ in Millions)	FY 2009 Actual	FY 2010 Estimate	FY 2011 Base Estimate	FY 2011 OCO Estimate	FY 2011 Total Estimate	FY 2012 Estimate	FY 2013 Estimate	FY 2014 Estimate	FY 2015 Estimate	Cost To Complete	Total Cost
9999: <i>Congressional Adds</i>	31.913	46.845	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	172.667
Quantity of RDT&E Articles	0	0	0	0	0	0	0	0	0		
A. Mission Description and Budget Item Justification Congressional Adds											
B. Accomplishments/Planned Program (\$ in Millions)											
							FY 2009	FY 2010			
Congressional Add: Biocidal Wound Dressings <i>FY 2010 Plans:</i> This project will procure for testing and evaluation low levels of wound dressings, which are able to remove more than 99.999% of bacteria, fungi and viruses passing through their media.							0.000	1.195			
Congressional Add: Deployment Health and Chronic Disease Surveillance <i>FY 2010 Plans:</i> This project will demonstrate and evaluate patient encounter points in the Arlington Health Clinics and provide lessons learned for health care record surveillance to the Department of Defense as a demonstration project. This demonstration will leverage civilian operational clinical settings in Northern Virginia and then evaluated for deployment applicability within the DoD.							0.000	0.797			
Congressional Add: Integrated Psycho-Social Health Care Demonstration Program							0.000	0.996			

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B. Accomplishments/Planned Program (\$ in Millions)		
	FY 2009	FY 2010
<i>FY 2010 Plans:</i> This project will enhance healthcare for US service members and their families, and will proactively address their unique psychological healthcare needs through the use of industry-leading targeted population management models. it will target a pilot population of DoD beneficiaries within a designed Military Treatment Facility area.		
Congressional Add: Management of Lung Injury by Micronutrients <i>FY 2010 Plans:</i> Continue a pilot project that defined oxidative damage and inflammation in lung injury in military recruits and made a preliminary assessment of the effects of antioxidant micronutrient supplementation. The prospective, randomized double blind, placebo-controlled study will evaluate impact on respiratory disease, military readiness and quality of life, as well as laboratory data including antioxidant levels, markers of oxidative damage and inflammation.	0.000	1.195
Congressional Add: Multivalent Dengue Vaccine Program <i>FY 2010 Plans:</i> Continue work to manufacture the two vaccine mixture under Good Manufacturing Processes (GMP) conditions for a Phase I clinical investigation; conduct the Phase I clinical trial; and develop and test a single vaccine candidate that will produce neutralizing antibodies against all four serotypes in vaccinated animals.	0.000	1.275
Congressional Add: National Functional Geonomics Center Colloborating Site <i>FY 2010 Plans:</i> This project will establish the Penn State Center for Pharmacogenetics, which will create a repository of samples from every cancer patient that visits Penn State.	0.000	3.187

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B. Accomplishments/Planned Program (\$ in Millions)		
	FY 2009	FY 2010
Congressional Add: Simplified Orthopedic Surgery <i>FY 2010 Plans:</i> This project will further develop a computer-aided system that simplifies complex orthopedic surgical procedures by enabling them to be performed more accurately and quickly without using cumbersome and expensive mechanical jigs.	0.000	4.222
Congressional Add: Wound Care Research (transferred from Defense Health Program) <i>FY 2010 Plans:</i> This project will support research for the advancement of deep tissue and surface wound care. This will be accomplished through: a study of mechanisms for enhanced wound healing, novel methods for identifying wound healing progression, most efficacious treatment protocols, and novel therapeutic regimens. It will also explore the use of amnion-derived, multipotent progenitor cells for the treatment of acute wounds in a relevant animal model of acute injury. This will support molecular and cellular investigations and support of clinical studies that include biomarker and other analysis, which can be used to promote development of a Good Manufacturing Practice facility for the production of such unique cells important to positive healing outcomes.	0.000	12.946
Congressional Add: MILITARY DENTAL RESEARCH <i>FY 2009 Accomplishments:</i> Developed innovative designs for dental care and dental health for CONUS and OCONUS operations. Conducted critical research in development of rapid-read diagnostic tests and other protective measures that will help reduce the severity and number of casualties due to dental and other medical emergencies.	5.984	5.975

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B. Accomplishments/Planned Program (\$ in Millions)		
	FY 2009	FY 2010
<i>FY 2010 Plans:</i> Develop Antimicrobial Nanoemulsions to prevent infections in the field and evaluate the incidence and treatment required for dental emergencies occurring in deployed military personnel. Conduct critical research in development of antimicrobial resin.		
Congressional Add: Advanced Molecular Medicine Initiative <i>FY 2009 Accomplishments:</i> Conducted research to identify patients' individual cancer cells for a more effective and less toxic treatment of cancer and to understand more fully why the human immune system fails to recognize cancer cells. <i>FY 2010 Plans:</i> Continue research to improve cancer therapy primarily through improved understanding of cancer cell targeting, with a focus on radiation therapy, in addition to using pioneering efforts in the science of radiation resistance for potential casualties.	1.995	0.797
Congressional Add: ON-DEMAND CUSTOM BODY IMPLANTS/PROSTHESIS FOR INJU <i>FY 2009 Accomplishments:</i> Continued testing and evaluation of Phase I efforts to develop manufacturing methods and materials necessary for rapid prototyping and delivery of prostheses. Applied state-of-the-art CAD/CAM procedures to prosthesis manufacturing technology. <i>FY 2010 Plans:</i> Continue testing and evaluation of Phase I efforts to develop manufacturing methods and materials necessary for rapid prototyping and delivery of prostheses. Apply state-of-the-art CAD/CAM procedures to prosthesis manufacturing technology.	1.596	1.593

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B. Accomplishments/Planned Program (\$ in Millions)		
	FY 2009	FY 2010
Congressional Add: HAMPTON UNIVERSITY CANCER TREATMENT INITIATIVE <i>FY 2009 Accomplishments:</i> Continued research on advanced technologies for diagnosis and treatment of cancer. Particular emphasis has been placed on military and military veterans. <i>FY 2010 Plans:</i> Continue research on advanced technologies for diagnosis and treatment of cancer. Particular emphasis will be placed on military and military veterans.	7.977	3.983
Congressional Add: Mobile Oxygen, Venilation & External Suction (Mo <i>FY 2009 Accomplishments:</i> Initiated reconfiguration of Low Rate Initial Production (LRIP) units Monitoring, Oxygen Ventilation and External Suction System (MOVES) for human factors, weight, cube and cost. Reconfiguration of MOVES was specifically targeted to reduce weight and cost. Incorporated requirements from other services into LRIP units as part of the planned next generation research and development spiral. Designed configurations based on feedback from the warfighter and joint requirements for en-route care. <i>FY 2010 Plans:</i> Continue reconfiguration of Low Rate Initial Production (LRIP) units Monitoring, Oxygen Ventilation and External Suction System (MOVES) for human factors, weight, cube and cost. Reconfiguration of MOVES is specifically targeted to reduce weight and cost. Incorporate requirements from other services into LRIP units as part of the planned next generation research and development spiral. Design configurations based on feedback from the warfighter and joint requirements for en-route care.	1.197	2.709
Congressional Add: US NAVY PANDAMIC INFLUENZA VACCINE PROGRAM	1.596	1.593

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B. Accomplishments/Planned Program (\$ in Millions)		
	FY 2009	FY 2010
<i>FY 2009 Accomplishments:</i> Determine incidence and severity of pandemic influenza in active duty and reserve DoD personnel and determine the extent to which this disease may be preventable through vaccine development. <i>FY 2010 Plans:</i> Initiate research to develop safe and effective pandemic influenza vaccines. Develop strategies to assure and protect the health of military personnel with these vaccines.		
Congressional Add: PENN STATE CANCER INSTITUTE <i>FY 2009 Accomplishments:</i> Continued research and development efforts in support of the new Penn State Cancer Institute (PSCI) and the focus on expansion of translational cancer research capabilities in the areas of the breast, colon, and treatment of cancer.	2.792	0.000
Congressional Add: Composite Tissue Transplantation for Combat Wounded <i>FY 2009 Accomplishments:</i> Initiated effort to establish a multidisciplinary center for the systematic study of composite tissue transplantation. This center will conduct mechanistic studies on the immune response and rejection of transplanted tissues and establish a capability to conduct clinical trials in hand transplantation. The program will include a strategy to collect and analyze clinical data and materials to further the knowledge base on composite tissue transplants and will be used to develop novel immunosuppressive treatments.	1.995	1.992

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B. Accomplishments/Planned Program (\$ in Millions)		
	FY 2009	FY 2010
<i>FY 2010 Plans:</i> These funds will be executed through an existing cooperative agreement through the National Business Center to Emory University. The FY 10 funds will be used to conduct clinical trials for hand transplants.		
Congressional Add: Heal The Force <i>FY 2009 Accomplishments:</i> Ensured continued delivery of quality product and services to West Virginia clinics that support rural health and provide additional capabilities and features tailored to this state. Examples of these features are additional chronic disease registries guided by national standards and local clinical input, ePrescribing, and enhanced patient education and support the expansion of HEALTheWV program in collaboration with the National Technology Transfer Center.	2.792	0.000
Congressional Add: Topical Homostat Effectiveness Study <i>FY 2009 Accomplishments:</i> Designed and tested medical technologies and agents that decrease battlefield fatalities. These followed a review of existing commercial over-the-shelf hemostatic products.	0.798	0.000
Congressional Add: US Navy Cancer Vaccine Program <i>FY 2009 Accomplishments:</i> Began development of a novel prostate cancer vaccine in conjunction with Oncbiomune, LLC and supported the development of an IND submission needed for FDA approval. Initiated a Phase IA/B clinical trial at the VA San Diego Healthcare System, located in San Diego, CA. US military veterans who have received previous treatment (surgery, radiation or radioactive seed implants) and now have a rising PSA participate in the study.	2.393	2.390

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B. Accomplishments/Planned Program (\$ in Millions)		
	FY 2009	FY 2010
<i>FY 2010 Plans:</i> Continue development of a novel prostate cancer vaccine in conjunction with Oncbiomune, LLC. Continue a Phase IA/B clinical trial at the VA San Diego Healthcare System, located in San Diego, CA. US military veterans who have received previous treatment (surgery, radiation or radioactive seed implants) and now have a rising PSA participate in the study.		
Congressional Add: Disposable Biocidal Medical Masks for NAMRU Evalua <i>FY 2009 Accomplishments:</i> Conducted field and laboratory evaluation of human factors and efficacy of N95 Respirator with antimicrobial protection (Triosyn). Masks will be evaluated for form, fit, and function in select environments where conventional masks are used. Focus will be on field evaluations where infection control is a critical issue.	0.798	0.000
Congressional Adds Subtotals	31.913	46.845
C. Other Program Funding Summary (\$ in Millions)		
N/A		
D. Acquisition Strategy		
N/A		
E. Performance Metrics		
Congressional Adds		

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